

1029258



Science For A Better Life



September 26, 2016

U.S. Environmental Protection Agency

Document Processing Desk - 6(a)(2)

Office of Pesticide Programs - 7504P

Room S-4900, One Potomac Yard

Arlington, VA 22202-4501

SUBJECT: 6(a)(2) Follow-Up Incidents Accumulated from August 1, 2016 through
August 30, 2016.

Dear Sir/Madam:

Please find additional Bayer Animal Health Division 6(a)(2)
incidents accumulated from August 1, 2016 through August 30, 2016. These
incidents are being submitted in accordance with FIFRA Section 6(a)(2).

Bayer
Animal Health
P.O. Box 390
Shawnee, Mission, KS
66201-0390

Please feel free to contact me at chris.ensley@bayer.com or at
913-268-2730, if I can provide any additional information, or to be any
further assistance.

Respectfully,

BAYER

ANIMAL HEALTH DIVISION

Chris Ensley

Regulatory Affairs Specialist

Encl: Bayer report nos:

2016-US0037188

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Mr Fed Brawdy		Submission date. 09-26-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0037188
	Address PA USA			Address USA -001	
	Phone # (412) 462-8842			Phone #	
	Incident Status: Update If update, include date of original submission 07-26-2016	Location and date of incident. 06-17-2016		Date registrant became aware of incident. 06-29-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-155		EPA Registration # (Product 2)		EPA Registration # (Product 3)
	A.I. (s) Flumethrin-Imidacloprid		A.I. (s)		A.I. (s)
	Product 1 name Seresto Small Dog		Product 2 name		Product 3 name
	Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?
	Formulation Collar		Formulation		Formulation
	Evidence label directions were not followed? Yes Intentional misuse No		Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).		Situation (act of using product) : (examples including mixing/loading, reentry application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
Applicator certified PCO? No					
Row 3 Incident Circumstances	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description		Brief description of incident circumstances		

ED 005739D 00013706-00002

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 2 of 3

Internal ID # 2016-U50037188

Brief description of incident circumstances

On 13-Jun-2016, a man, in unknown condition, with no known concomitant medical conditions, was exposed to an unknown amount of 1 Seresto Small Dog (Flumethrin-Imidacloprid) collar when he applied it to the dog and the dog was petted.

On approximately 17-Jun-2016, the man experienced swelling and pruritus on his hands at the exposure site.

On 23-Jun-2016, the man was evaluated by a physician who performed an unspecified blood work panel. Results were within normal limits.

On 30-Jun-2016, the man was re-evaluated by a physician and referred to a dermatologist.

On 01-Jul-2016, the man was evaluated by a dermatologist who diagnosed an unspecified reaction to the active ingredients/application site reaction NOS. The dermatologist treated the man with an unspecified anti-pruritus cream topically and unspecified steroids orally.

On approximately 08-Jul-2016, the signs resolved.

No further information expected; case closed.

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Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 3 of 3

Demographic information: Age: Unknown Sex : Male Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 4 Days *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Application site reaction NOS Application site pruritus Application site oedema		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			
<p>This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)</p> <div style="border: 1px solid black; height: 150px; width: 100%;"></div> <div style="border: 1px solid black; padding: 5px; width: fit-content; float: right;"> Internal ID # 2016-050037188 </div>			

* approximate

Version : 19-Sep-2016 at 19:22

ED_005739D_00013706-00004



Science For A Better Life



September 26, 2016

U.S. Environmental Protection Agency

Document Processing Desk - 6(a)(2)

Office of Pesticide Programs - 7504P

Room S-4900, One Potomac Yard

Arlington, VA 22202-4501

SUBJECT: 6(a)(2) Incidents Accumulated for Month of August, 2016

Dear Sir/Madam:

Please find additional Bayer Animal Health Division 6(a)(2) incidents accumulated during the month of August, 2016. These incidents are being submitted in accordance with FIFRA Section 6(a)(2).

Bayer
Animal Health

P.O. Box 390
Shawnee, Mission, KS
66201-0390

Please feel free to contact me at chris.ensley@bayer.com or 913-268-2730, if I can provide any additional information, or to be any further assistance.

Respectfully,

BAYER

ANIMAL HEALTH DIVISION

Chris Ensley

Regulatory Affairs Specialist

Encl: Bayer report nos:

2016-US0047038, 2016-US0047042, 2016-US0047057, 2016-US0048690,
2016-US0049122, 2016-US0049129, 2016-US0049534, 2016-US0049535,
2016-US0050101, 2016-US0050225, 2016-US0051318, 2016-US0052175,
2016-US0052896, 2016-US0053593, 2016-US0054520, 2016-US0054733

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Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Ms Lisa Morgan	Submission date. 09-26-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0047038
	Address Erie PA 16507 USA		Address USA -002	
	Phone # (814) 881-8299		Phone #	
	Incident Status: New If update, include date of original submission	Location and date of incident. 08-02-2016	Date registrant became aware of incident. 08-02-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-143	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Imidacloprid-Permethrin-Pyriproxyfen	A.I. (s)	A.I. (s)	
	Product 1 name K9 Advantix II Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Topical solution	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) : (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 5		

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Internal ID # 2016-U50047038

Brief description of incident circumstances

On 02-Aug-2016, a 32 year old, pregnant woman, of unknown condition, with no known concomitant medical conditions, who was taking an unspecified prenatal vitamin orally since approximately May-2016, was exposed to an unknown amount of K9 Advantix II Large Dog (Imidacloprid-Permethrin-Pyriproxyfen) when she applied it to her dog, then kissed the dog on the face. No known direct exposure occurred.

Immediately post exposure, the woman tasted the product on her lips (bad taste). The woman washed her mouth out with an unspecified soap and brushed her teeth with an unspecified toothpaste.

Approximately 5 minutes post onset of the sign, the woman recovered without medical intervention.

No further information expected; case closed.

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Version : 8-Aug-2016 at 10:57

ED_005739D_00013706-00007

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Demographic information: Age: 32 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Yes	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Minutes *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Taste disorder		If lab tests were performed, list test names and results(if available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1			
Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			
This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)			
<div style="text-align: right;"> Internal ID # 2016-US0047038 </div>			

* approximate


Version : 8-Aug-2016 at 10:57

ED_005739D_00013706-00008

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 1 of 3

Row 1 Administrative Data	Reporter Name Ms Amanda Not Provided	Submission date: 09-26-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0047042
	Address CA USA	Address USA - 003		
	Phone # (760) 500-7447	Phone #		
	Incident Status: New If update, include date of original submission	Location and date of incident. 08-02-2016	Date registrant became aware of incident. 08-02-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-155	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Flumethrin-Imidacloprid	A.I. (s)	A.I. (s)	
	Product 1 name Seresto (unspecified)	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ? No	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Collar	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).		Situation (act of using product) (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 		

Version : 8-Aug-2016 at 14:14

ED_005739D_00013706-00009

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Internal ID # 2016-U50047042

Brief description of incident circumstances

On an unspecified date in approximately 2016, a 3 year old, male, child, in unknown condition, with no known concomitant medical conditions, was exposed to an unknown amount of 1 Seresto (unspecified) (Flumethrin-Imidacloprid) collar while living in the home with a dog that had it applied the same day. It is unknown if direct exposure occurred.

At an unspecified time post exposure, on 02-Aug-2016, the child experienced a seizure that resolved within approximately 5 minutes. The child was examined by an emergency room physician, however, no diagnosis was made. It is unknown if any treatments beyond observation were performed.

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Version : 8-Aug-2016 at 14:14

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Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Demographic information: Age: 3 Year(s) Sex : Male Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: Unknown	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Convulsion		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1			
Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			
This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)			
<div style="text-align: right; margin-right: 100px;">10</div> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin-left: auto;"> Internal ID # 2016-US0047042 </div>			

Version : 8-Aug-2016 at 14:14

ED_005739D_00013706-00011

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Mr David Eli	Submission date. 09-26-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0047057
	Address CA USA		Address USA -004	
	Phone # (714) 366-0938		Phone #	
	Incident Status: New If update, include date of original submission	Location and date of incident. 08-02-2016	Date registrant became aware of incident. 08-02-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-125	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Imidacloprid-Pyriproxyfen	A.I. (s)	A.I. (s)	
	Product 1 name Advantage II Medium Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Topical solution	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) : (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 		

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Internal ID # 2016-US0047057

Brief description of incident circumstances

On 02-Aug-2016, a man, of unknown condition, with no known concomitant medical conditions, was exposed to an unknown amount of Advantage II Medium Dog (Imidacloprid-Pyriproxyfen) when he applied it to his dog, then ate a sandwich. No known direct exposure occurred.

Approximately 3 hours post exposure, the man experienced abdominal discomfort, abdominal cramps, and a headache. The man took unspecified medications and approximately 1 hour post medication administration, the headache resolved.

The man was not examined by a physician and the abdominal signs continued.

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Version : 8-Aug-2016 at 07:49

ED_005739D_00013706-00013

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Demographic information: Age: Unknown Sex : Male Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 3 Hours *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Abdominal pain Abdominal pain Headache	If lab tests were performed, list test names and results(If available submit report). None reported	
Exposure data: Amount of pesticide: Unknown Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			
This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)			
<div style="border: 1px solid black; padding: 5px; width: fit-content; margin-left: auto;"> Internal ID # 2016-US0047057 13 </div>			

* approximate

Version : 8-Aug-2016 at 07:49

ED_005739D_00013706-00014

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 1 of 3

Row 1 Administrative Data	Reporter Name Ms Wanda Griffin	Submission date. 09-26-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0048690
	Address 139 Anchor St Portsmouth VA 23702 USA		Address USA -005	
	Phone # (757) 572-3260		Phone #	
	Incident Status: New If update, include date of original submission	Location and date of incident. 08-08-2016	Date registrant became aware of incident. 08-08-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-142	EPA Registration # (Product 2)		EPA Registration # (Product 3)
	A.I. (s) Imidacloprid-Permethrin- Pyriproxyfen	A.I. (s)		A.I. (s)
	Product 1 name K9 Advantix II Medium Dog	Product 2 name		Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?
	Formulation Topical solution	Formulation		Formulation
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).		Situation (act of using product) : (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 14		

Version : 12-Aug-2016 at 07:00

ED_005739D_00013706-00015

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Internal ID # 2016-US0048690

Brief description of incident circumstances

On 08-Aug-2016, a 53 year old, woman, in unknown condition, with concomitant medical conditions of diabetes and anxiety, who is on glucotrol, metformin Hcl and an unspecified anxiety medication orally and unspecified injections since approximately 2016, was exposed to an unknown amount of K9 Advantix II Medium Dog (Imidacloprid-Permethrin-Pyriproxyfen) when she applied it to her 2 dogs and got some of the product on 3 unspecified fingers on an unspecified hand.

Immediately post exposure, the woman experienced short, shallow, slow breathing (dyspnea) and difficulty speaking (speech disorder NOS). The woman washed her hands twice with an unspecified hand soap.

The woman was not examined by a physician and the signs continued.

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Version : 12-Aug-2016 at 07:00

ED_005739D_00013706-00016

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 3 of 3

Demographic information: Age: 53 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?			
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Minutes *				
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Speech disorder NOS Dyspnoea		If lab tests were performed, list test names and results(If available submit report). None reported			
Exposure data: Amount of pesticide: Unknown per 1						
Expose duration: 0 Days Patient weight: Unknown						
Human severity category H-C						
This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)						
<div style="text-align: right;"> <table border="1"> <tr> <td>Internal ID #</td> <td rowspan="2">16</td> </tr> <tr> <td>2016-US0048690</td> </tr> </table> </div>				Internal ID #	16	2016-US0048690
Internal ID #	16					
2016-US0048690						

* approximate

Version : 12-Aug-2016 at 07:00

ED_005739D_00013706-00017

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Ms Karen Ferraro	Submission date. 09-26-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0049122
	Address 62 Winkfield Rd. RUTLAND Vermont 05701 USA		Address USA - 006	
	Phone # (802) 773-1716		Phone #	
	Incident Status: New If update, include date of original submission	Location and date of incident. 08-06-2016	Date registrant became aware of incident. 08-09-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-155	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Flumethrin-Imidacloprid	A.I. (s)	A.I. (s)	
	Product 1 name Seresto Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Collar	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) : (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 17		

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Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Internal ID # 2016-U50049122

Brief description of incident circumstances

On 30-Jul-2016, a woman, in unknown condition, with concomitant medical conditions of asthma and allergies, was exposed to an unknown amount of 1 Seresto Large Dog (Flumethrin-Imidacloprid) collar when she applied it to her dog and removed it each night.

On approximately 06-Aug-2016, the woman experienced headaches, muscle weakness, confusion, and breathing problems (dyspnea).

On approximately 07-Aug-2016, the signs worsened.

On 08-Aug-2016, the owner removed the collar from the dog and put it in her garage.

The woman was not examined by a physician and the sign continued.

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Version : 11-Aug-2016 at 18:53

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 3 of 3

Demographic information: Age: 20-64 Years Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Weeks *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) No therapy. observation	List signs/symptoms/adverse effects Headache Muscle weakness NOS Mental confusion Dyspnoea		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1			
Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			
This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)			
<div style="text-align: right;"> Internal ID # 2016-US0049122 </div> <div style="font-size: 2em; margin-left: 100px;">19</div>			

* approximate

Version : 11-Aug-2016 at 18:53

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Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 1 of 3

Row 1 Administrative Data	Reporter Name Ms Sharon not provided	Submission date. 09-26-2016	Contact person (if different than reporter) not applicable	Internal ID # 2016-US0049129
	Address NE USA		Address USA - 007	
	Phone # (402) 376-2525		Phone #	
	Incident Status: New If update, include date of original submission	Location and date of incident. 08-09-2016	Date registrant became aware of incident. 08-09-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-170	EPA Registration # (Product 2)		EPA Registration # (Product 3)
	A.I. (s) Permethrin-PBO	A.I. (s)		A.I. (s)
	Product 1 name Permethrin CDS Pour-on	Product 2 name		Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?
	Formulation Pour on	Formulation		Formulation
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).		Situation (act of using product) (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 20		

Version : 18-Aug-2016 at 06:41

ED_005739D_00013706-00021

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Internal ID # 2016-US0049129

Brief description of incident circumstances

On 09Aug2016, a 16 year old, girl, in unknown condition, with no known concomitant medical conditions, was exposed to an unknown amount of Permethrin CDS Pour-on (Permethrin-PBO) when she got the diluted product onto her fingers while applying the product to cattle.

Approximately 30 minutes post product exposure, the girl developed emesis, fatigue, shakiness, muscle cramps and pyrexia.

Approximately 12 hours post product exposure, the girl was evaluated by an emergency physician with continued symptoms and presented flushed. Blood work was performed. The results were unknown. No known treatments were instituted.

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Version : 18-Aug-2016 at 06:41

ED_005739D_00013706-00022

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Demographic information: Age: 16 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 30 Minutes *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Other therapy:Other test	List signs/symptoms/adverse effects Emesis Lethargy Systemic disorder NOS Hyperthermia Peripheral vascular disorder Muscle tremor		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1			
Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

2016-US0049129

22

* approximate

Version : 18-Aug-2016 at 06:41

ED_005739D_00013706-00023

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 1 of 3

Row 1 Administrative Data	Reporter Name Ms Jennifer Arnold	Submission date. 09-26-2016	Contact person (if different than reporter) Not Applilcable	Internal ID # 2016-US0049534
	Address Vestal NY 13850 USA		Address USA - 008	
	Phone # (607) 341-2220		Phone #	
	Incident Status: New If update, include date of original submission	Location and date of incident. 06-27-2016	Date registrant became aware of incident. 08-08-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-155	EPA Registration # (Product 2)		EPA Registration # (Product 3)
	A.I. (s) Flumethrin-Imidacloprid	A.I. (s)		A.I. (s)
	Product 1 name Seresto (unspecified)	Product 2 name		Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?
	Formulation Collar	Formulation		Formulation
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).		Situation (act of using product) : (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 23		

Version : 11-Aug-2016 at 14:53

ED_005739D_00013706-00024

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Internal ID # 2016-US0049534

Brief description of incident circumstances

On 25-Jun-2016, a woman, in unknown condition, with no known concomitant medical conditions, was accidentally exposed to an unknown amount of 2 Seresto (unspecified) (Flumethrin-Imidacloprid) collars on her hands when she applied them to her dogs and then continued to be secondarily exposed when the dogs slept in her bed with her and she pet the dogs.

On 27-Jun-2016, the woman experienced pruritus.

On an unspecified date post exposure, in 2016, the woman stopped allowing the dogs to sleep int the bed with her.

The woman was not examined by a physician and the pruritus continued, but was improved.

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Version : 11-Aug-2016 at 14:53

ED_005739D_00013706-00025

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Demographic information: Age: Unknown Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 2 Days	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Pruritus		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1			
Expose duration: Unknown Patient weight: Unknown			
Human severity category H-C			
This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)			
<div style="border: 1px solid black; padding: 5px; width: fit-content; margin-left: auto;"> Internal ID # 2016-US0049534 </div> <div style="font-size: 2em; margin-left: 10px;">25</div>			

Version : 11-Aug-2016 at 14:53

ED_005739D_00013706-00026

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 1 of 3

Row 1 Administrative Data	Reporter Name Ms Jennifer Arnold	Submission date. 09-26-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0049535
	Address Vestal NY 13850 USA		Address USA Part of - 008	
	Phone # (607) 341-2220		Phone #	
	Incident Status: New If update, include date of original submission	Location and date of incident. 06-27-2016	Date registrant became aware of incident. 08-08-2016	Was incident part of larger study? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-155	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Flumethrin-Imidacloprid	A.I. (s)	A.I. (s)	
	Product 1 name Seresto (unspecified)	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution?	Exposed to concentrate prior to dilution?	Exposed to concentrate prior to dilution?	
	Formulation Collar	Formulation	Formulation	
	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) : (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
Row 3 Incident Circumstances	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 26		

Version : 11-Aug-2016 at 15:00

ED_005739D_00013706-00027

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 2 of 3

Internal ID # 2016-US0049535

Brief description of incident circumstances

On 25-Jun-2016, a man, in unknown condition, with no known concomitant medical conditions, was secondarily exposed to an unknown amount of 2 Seresto (unspecified) (Flumethrin-Imidacloprid) collars after sleeping with 2 dogs that were each wearing one. It is unknown if direct exposure occurred with the collars.

On 27-Jun-2016, the man experienced pruritus.

The man was not examined by a physician and the sign continued.

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Version : 11-Aug-2016 at 15:00

ED_005739D_00013706-00028

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Demographic information: Age: Unknown Sex : Male Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 2 Days	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Pruritus		If lab tests were performed, list test names and results (If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1			
Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			
This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)			
<div style="text-align: right;"> Internal ID # 2016-US0049535 </div> <div style="font-size: 2em; margin-left: 10px;">28</div>			

Version : 11-Aug-2016 at 15:00

ED_005739D_00013706-00029

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Ms Marlene Rasmussen	Submission date. 09-26-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0050101
	Address 1725 242 St SE Unit 244 Bothell WA 98021 USA		Address USA - 009	
	Phone # (425) 483-5615		Phone #	
	Incident Status: New If update, include date of original submission	Location and date of incident. 08-09-2016	Date registrant became aware of incident. 08-12-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-141	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Imidacloprid-Permethrin-Pyriproxyfen	A.I. (s)	A.I. (s)	
	Product 1 name K9 Advantix II Small Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Topical solution	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) : (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 29		

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Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Internal ID # 2016-US0050101

Brief description of incident circumstances

On 07-Aug-2016, a 79 year old, woman, in unknown condition, with concomitant medical conditions of a history of a stroke and high cholesterol, was exposed to an unknown amount of K9 Advantix II Small Dog (Imidacloprid-Permethrin-Pyriproxyfen) when she applied it to her dog. No known direct exposure occurred.

On 09-Aug-2016, the individual bathed the dog with a liquid dish soap and applied vitamin e oil to the site where the K9 Advantix II was applied.

Approximately 9 hours post bathing and topical administration of vitamin e oil, the individual experienced feeling tired, heavy eyes (eye disorder NOS), trouble communicating, and confusion. The signs resolved approximately 4 hours post onset without medical intervention.

On 12-Aug-2016, the individual experienced a headache, so self administered an unspecified aspirin. The sign resolved approximately 2 hours post onset.

The individual was not examined by a physician.

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Version : 15-Aug-2016 at 15:39

ED_005739D_00013706-00031

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Demographic information: Age: 79 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? No	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 2 Days	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Lethargy Eye disorder NOS Speech problem Mental confusion Headache	If lab tests were performed, list test names and results (if available submit report). None reported	
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			
This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)			
<div style="text-align: right;"> <div>Internal ID #</div> <div>2016-US0050101</div> </div> <div style="font-size: 2em; margin-left: 10px;">31</div>			

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Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Row 1 Administrative Data	Reporter Name Ms Deb Pacheco	Submission date. 09-26-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0050225
	Address 1 Gee Ave Gloucester MA 01930 USA		Address USA -010	
	Phone # (978) 879-7046		Phone #	
	Incident Status: New If update, include date of original submission	Location and date of incident. 08-13-2016	Date registrant became aware of incident. 08-13-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-150	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Imidacloprid-Pyriproxyfen	A.I. (s)	A.I. (s)	
	Product 1 name Advantage II Kitten	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Topical solution	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) : (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 32		

Version : 16-Aug-2016 at 10:10

ED_005739D_00013706-00033

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Internal ID # 2016-US0050225

Brief description of incident circumstances

On 13-Aug-2016, a 57 year old, woman, in unknown condition, with no known concomitant medical conditions, who was administered unspecified medications since approximately 2016, was exposed to an unknown amount of Advantage II Kitten (Imidacloprid-Pyriproxyfen) when she applied the product to multiple kittens, handled the kittens while the product was wet, then took unspecified oral medications without washing her hands first.

Approximately 30 minutes post exposure, the woman experienced a burning throat, numb lips, and a dry mouth.

The woman was not examined by a physician and the signs continued.

33

Version : 16-Aug-2016 at 10:10

ED_005739D_00013706-00034

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Demographic information: Age: 57 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 30 Minutes *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Laryngeal irritation Hyposalivation Hypoaesthesia		If lab tests were performed, list test names and results (If available submit report). None reported
Exposure data: Amount of pesticide: Unknown			
Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

2016-US0050225

34

* approximate

Version : 16-Aug-2016 at 10:10

ED_005739D_00013706-00035

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Row 1 Administrative Data	Reporter Name Ms Ann Holland	Submission date. 09-26-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0051318
	Address 6509 Arbor Grande Way Raleigh NC 27609 USA		Address USA - 011	
	Phone # (919) 781-0168		Phone #	
	Incident Status: New If update, include date of original submission	Location and date of incident. 08-17-2016	Date registrant became aware of incident. 08-17-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-144	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Imidacloprid-Permethrin- Pyriproxyfen	A.I. (s)	A.I. (s)	
	Product 1 name K9 Advantix II Extra Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Topical solution	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) : (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 35		

Version : 19-Aug-2016 at 12:46

ED_005739D_00013706-00036

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Internal ID # 2016-US0051318

Brief description of incident circumstances

On 17-Aug-2016, a 70 year old woman, in unknown condition, with concomitant medical conditions of hypertension, a thyroid disorder, and high cholesterol, was exposed to an unknown amount of K9 Advantix II Extra Large Dog (Imidacloprid-Permethrin-Pyriproxyfen) when she applied it to her dog, rubbed the product in with her fingers, washed her hands with an unspecified soap, put her fingers in her mouth, and may have ingested some of the product.

Approximately 5 minutes post exposure, the woman experienced a bad taste in her mouth.

The woman was not examined by a physician and the sign continued.

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Version : 19-Aug-2016 at 12:46

ED_005739D_00013706-00037

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Demographic information: Age: 70 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 5 Minutes *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Taste disorder		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1			
Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			
This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)			
<div style="text-align: right;"> <div>Internal ID #</div> <div>2016-US0051318</div> <div style="font-size: 2em; margin-left: 10px;">37</div> </div>			

* approximate

Version : 19-Aug-2016 at 12:46

ED_005739D_00013706-00038

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 1 of 3

Row 1 Administrative Data	Reporter Name Ms Deborah Bennett	Submission date. 09-26-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-U50052175
	Address 615 Bennett Mountatin Road Alderson WV 24910 USA		Address USA -012	
	Phone # (304) 392-2401		Phone #	
	Incident Status: New If update, include date of original submission	Location and date of incident. 07-01-2016	Date registrant became aware of incident. 08-19-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-155	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Flumethrin-Imidacloprid	A.I. (s)	A.I. (s)	
	Product 1 name Seresto Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Collar	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).		Situation (act of using product) : (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 38		

Version : 31-Aug-2016 at 15:46

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Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 2 of 3

Internal ID # 2016-US0052175

Brief description of incident circumstances

On 01-May-2016, a 55 year old, woman, in unknown condition, with concomitant medical conditions of: allergies, sensitive skin, a history of pericardial effusion, a memory disorder and a seizure disorder, was exposed to an unknown amount of 1 Seresto Large Dog (Flumethrin-Imidacloprid) after it was applied it to her dog by another person. No known direct exposure to the collar occurred. The woman continued to be secondarily exposed daily when she touched the dog that was wearing the collar.

On approximately 01-Jul-2016, the woman experienced a generalized allergic reaction, dyspnea, tachypnea, erythema, lethargy and a rash on her forearms. The signs resolved within approximately 5 hours.

On approximately 02-Jul-2016, the clinical signs continued to recur and resolve daily.

On an unspecified date in Jul-2016, the woman was examined by a physician who treated her with clobetasol topically.

On approximately 23-Aug-2016, the woman removed the collar.

On 24-Aug-2016, the woman experienced edema, dyspnea and a rash. The woman was examined by an emergency room physician. It is unknown what diagnostics or treatments were performed. The signs continued to recur and resolve unchanged.

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Version : 31-Aug-2016 at 15:46

ED_005739D_00013706-00040

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Demographic information: Age: 55 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 8 Weeks *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Other therapy	List signs/symptoms/adverse effects Hypersensitivity reaction Dyspnoea Tachypnoea Erythema Lethargy Dermatitis and eczema Oedema NOS	If lab tests were performed, list test names and results (If available submit report). None reported	
Exposure data: Amount of pesticide: Unknown per 1			
Exposure duration: Unknown Patient weight: Unknown			
Human severity category H-C			
<p>This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)</p> <div style="border: 1px solid black; height: 150px; width: 100%;"></div> <div style="border: 1px solid black; padding: 5px; width: fit-content; float: right;"> Internal ID # 2016-US0052175 </div> <div style="font-size: 40px; margin-left: 20px; margin-top: -100px;">40</div>			

* approximate

Version : 31-Aug-2016 at 15:46

ED_005739D_00013706-00041

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Row 1 Administrative Data	Reporter Name Ms Ann Santos	Submission date. 09-26-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0052896
	Address 109 Nicol Drive Reading PA 19606 USA		Address USA -013	
	Phone # (484) 824-1049		Phone #	
	Incident Status: New If update, include date of original submission	Location and date of incident. 08-23-2016	Date registrant became aware of incident. 08-23-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-155	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Flumethrin-Imidacloprid	A.I. (s)	A.I. (s)	
	Product 1 name Seresto Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Collar	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) : (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 41		

Version : 26-Aug-2016 at 13:03

ED_005739D_00013706-00042

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Internal ID # 2016-US0052896

Brief description of incident circumstances

On 23-Aug-2016, a 64 year old, woman, in unknown condition, with concomitant medical conditions of a history of cancer, was exposed to an unknown amount of 1 Seresto Large Dog (Flumethrin-Imidacloprid) collar when she removed the collar from the tin to look at it and then replaced it into the tin.

Immediately post exposure, the woman washed her hands with an unspecified soap.

Approximately 15 minutes post exposure, the woman experienced a headache, blurred vision and muscle weakness.

Approximately 2 hours post onset of signs, the signs resolved without medical intervention.

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Version : 26-Aug-2016 at 13:03

ED_005739D_00013706-00043

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Demographic information: Age: 64 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 15 Minutes *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Headache Abnormal vision Muscle weakness NOS	If lab tests were performed, list test names and results(If available submit report). None reported	
Exposure data: Amount of pesticide: Unknown per 1			
Expose duration: 0 Days			
Patient weight: Unknown			
Human severity category H-C			
This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)			
<div style="border: 1px solid black; padding: 5px; width: fit-content; margin-left: auto;"> Internal ID # 2016-US0052896 </div> <div style="font-size: 2em; margin-left: 10px;">43</div>			

* approximate

Version : 26-Aug-2016 at 13:03

ED_005739D_00013706-00044

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 1 of 3

Row 1 Administrative Data	Reporter Name Ms. Cindy Morrison	Submission date. 09-26-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-U50053593
	Address 40 Irwin Place Hazlet NJ 07730 USA	Address USA -014		
	Phone # (732) 264-7308	Phone #		
	Incident Status: New If update, include date of original submission	Location and date of incident. 08-17-2016	Date registrant became aware of incident. 08-25-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-155	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Flumethrin-Imidacloprid	A.I. (s)	A.I. (s)	
	Product 1 name Seresto Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Collar	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).		Situation (act of using product) : (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 44		

Version : 29-Aug-2016 at 10:11

ED_005739D_00013706-00045

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 2 of 3

Internal ID # 2016-US0053593

Brief description of incident circumstances

On 15-Aug-2016, a 5 year old girl, in unknown condition, with no known concomitant medical conditions, was exposed to an unknown amount of 1 Seresto Large Dog (Flumethrin-Imidacloprid) collar when her mother applied it to the dog. No known direct exposure occurred.

On 17-Aug-2016, the child awoke and experienced a pruritic rash that looked like heat rash, on an unspecified wrist and leg.

On 20-Aug-2016, the rash worsened. The child was examined by a physician and treated with an unspecified steroid orally. The mother removed the collar from the dog.

The signs improved but continued.

45

Version : 29-Aug-2016 at 10:11

ED_005739D_00013706-00046

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Demographic information: Age: 5 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 2 Days	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Dilute/irrigate/wash;Stero	List signs/symptoms/adverse effects Dermatitis and eczema Miliaria		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1			
Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			
This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)			
<div style="text-align: right;"> Internal ID # 2016-US0053593 46 </div>			

Version : 29-Aug-2016 at 10:11

ED_005739D_00013706-00047

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 1 of 3

Row 1 Administrative Data	Reporter Name Ms Karen Tice	Submission date. 09-26-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0054520
	Address 11 Granite Rd Ossipee NH 03864 USA		Address USA -015	
	Phone # (603) 651-6346		Phone #	
	Incident Status: New If update, include date of original submission	Location and date of incident. 08-25-2016	Date registrant became aware of incident. 08-29-2016	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-155	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Flumethrin-Imidacloprid	A.I. (s)	A.I. (s)	
	Product 1 name Seresto Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Collar	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) : (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 47		

Version : 31-Aug-2016 at 06:43

ED_005739D_00013706-00048

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Internal ID # 2016-US0054520

Brief description of incident circumstances

On 24-Aug-2016, a 40 year old, woman, in unknown condition, with concomitant medical conditions of allergies, was exposed to an unknown amount of 1 Seresto Large Dog (Flumethrin-Imidacloprid) when she held a grooming client's dog, who was wearing the collar, against her neck.

On 25-Aug-2016, the woman experienced a rash at the exposure site on her neck and at an unspecified area on her shoulder. The woman applied a triamcinolone cream topically to the area. The sign improved but continued.

On 29-Aug-2016, the woman was examined by a physician who diagnosed an allergic reaction and treated with a prednisone pack.

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Version : 31-Aug-2016 at 06:43

ED_005739D_00013706-00049

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Demographic information: Age: 40 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Days	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Steroids, Oral;Steroids,	List signs/symptoms/adverse effects Application site inflammation Dermatitis and eczema Hypersensitivity reaction		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

2016-US0054520

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Version : 31-Aug-2016 at 06:43

ED_005739D_00013706-00050

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Page 1 of 3

Row 1 Administrative Data	Reporter Name Ms Sarah Hughes	Submission date 09-26-2016	Contact person (if different than reporter) Not Applicable	Internal ID # 2016-US0054733
	Address NV USA	Address USA -016		
	Phone # (774) 551-6341		Phone #	
	Incident Status: New If update include date of original submission	Location and date of incident 08-26-2016	Date registrant became aware of incident 08-30-2016	Was incident part of larger study? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 11556-155	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) Flumethrin-Imidacloprid	A.I. (s)	A.I. (s)	
	Product 1 name Seresto Large Dog	Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Collar	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) : (examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances 50		

Version : 3-Sep-2016 at 18:12

ED_005739D_00013706-00051

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Internal ID # 2016-US0054733

Brief description of incident circumstances

On 26-Aug-2016, a 57 year old, woman, in unknown condition, with concomitant medical conditions of allergies and celiacs disease (digestive tract disorder, was exposed to an unknown amount of 1 Seresto Large Dog (Flumethrin-Imidacloprid) collar when she touched a dog that was wearing the collar. It is unknown if direct contact was made with the collar.

Approximately 8 hours post exposure, the woman experienced a rash on her neck.

On 27-Aug-2016, the rash worsened. The woman was examined by a physician at an urgent care facility and was diagnosed with poison ivy (allergic reaction) and was administered an unknown dose of prednisone by mouth daily and an unspecified antihistamine by mouth daily.

On 30-Aug-2016, the rash spread to the right side of her body, the woman experienced blisters on her lips and face and edema to her eyelids. The woman was re-examined by a physician who continued treatment with prednisone orally and increased the dose of the unspecified antihistamine. The physician diagnosed a continued allergic reaction. The signs continued.

5 |

Version : 3-Sep-2016 at 18:12

ED_005739D_00013706-00052

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

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Demographic information: Age: 57 Year(s) Sex : Female Occupation (if relevant)	Exposure route: Other	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ? Unknown to Company	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 8 Hours *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Antihistamines;Steroids,	List signs/symptoms/adverse effects Dermatitis and eczema Bullous disorder Blepharitis Hypersensitivity reaction	If lab tests were performed, list test names and results(If available submit report). None reported	
Exposure data: Amount of pesticide: Unknown per 1 Expose duration: 0 Days Patient weight: Unknown			
Human severity category H-C			
This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)			
<div style="border: 1px solid black; padding: 5px; width: fit-content; margin-left: auto;"> Internal ID # 2016-US0054733 </div> <div style="font-size: 2em; margin-left: 10px;">52</div>			

* approximate

Version : 3-Sep-2016 at 18:12

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